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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CHOI, FRANK I	
ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/089,846	CARTER, JOHN	
	Examiner	Art Unit	
	FRANK I. CHOI	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *105,106,108,124,125,127-130,132-135,165 and 166* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *105,135 and 166* is/are allowed.

6)☒ Claim(s) *124,125,127-130 and 132-134* is/are rejected.

7)☒ Claim(s) *106,108 and 165* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/12/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 105, 135 and 166 are allowed over the prior art.

Information Disclosure Statement

The information disclosure statement filed 1/12/2009 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because a copy of the foreign patent document was not provided. The translation of a foreign patent document is not a foreign patent document. In any case, the EP 0511895 reference was already listed in a PTO-892 (8/11/2008). As such, the information disclosure statement is redundant. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Objections

Claims 106, 108, 124, 125, 127-130, 132-134, 165 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claims 106, 108, 165 appear to indicate that the composition need only contain recited active ingredient whereas four active ingredients are required in the independent claim none of which are the recited active ingredient. The examiner suggests that "further contains" be used instead of "contains". Claims 124, 125, 127-130, 132-134 recite "composition comprises" but do not indicate that claims are limited specific active ingredients as sole active ingredients as set

forth in claim 105. Since the composition as whole is referred to by the term "comprising" as opposed to modifications to only the amounts of the ingredients it appears that the composition is open to other active ingredients. Claim 125 appears to not require the manganese ingredient as the claim refers to the composition as a whole whereas the claim on which it is dependent required that the composition as a whole contain the manganese ingredient. The Examiner suggests that where only modifications in the amounts of an ingredient in the composition are recited that the claim not refer to the composition as a whole but only the modified amounts of the ingredients; For example, "wherein the amount of . . . ranges from" or "wherein . . . is present in the amount of", or similar language without using "composition comprising" in the claim. The Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 124, 125, 127-130, 132-134 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 124, 125, 127-130, 132-134 recite the limitation "comprises . . . equivalent amount of active ingredient when a physiological source of assimilable . . . other than . . . is used " and also does not indicate that the active ingredients are the sole active ingredients after the transitional phrase "comprises". There is insufficient antecedent basis for this limitation in the claim as the claim 104 on which the same are dependent only allows copper gluconate or copper

orotate, sodium salicylate, vitamin C, manganese gluconsate or manganese orotate, iron gluconate or iron orotate, sublimed sulphur and zinc gluconate or zinc orotate. No other pharmaceutically active compents are allowed.

Claims 127, 128, 132, 133 recite the limitation "sulphur". There is insufficient antecedent basis for this limitation in the claim for the same reasons as above. Specifically the limitation "sulphur" is not limited to "sublimed sulphur" as required in claim 104.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 124,125,127-130, 132-134 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al. (US Pat. 5,654,011) in view of Riley et al. (US Pat. 5,948,443), Klampfer et al., EP 0511895, Wawretschek et al. (US Pat. 4,061,741), DE 2457424, Herschler (US Pat. 4,514,421), Herschler (US Pat. 4,616,039), Memnon et al. and Maramag et al..

Jackson et al. disclose compositions and methods for providing dietary supplements to med the needs of pre-perimenopausal women, including pregnant women, and to reduce the risk of cancer comprising copper, manganese, zinc, iron and vitamin C (Column 2, lines 25-51, Column 4, lines 13-23, Column 8, lines 30-68).

Riley et al. discloses a composition and method of reducing the risk of cancer by providing dietary supplements to women which comprise aspirin or bioequivalent forms, such as

salicylic acid or other salicylates, iron, zinc, manganese, copper and Vitamin C (Column 9, lines 30-55, Column 21, lines 7-63,Table III).

EP 0511895 discloses a composition containing ascorbic acid, copper gluconate and manganese gluconate which has anti-cancer activity (Abstract, Page 4)

Klampfer et al. disclose that nonsteroidal anti-inflammatory agents are known for their chemopreventitive activity and that sodium salicylate and aspirin induce apoptosis or leukemia cells (See pages 2386, 2393).

Wawretschek et al. disclose that the analgesic efficiency of sodium salicylate can be reinforced by combining with a salt of orotic acid (Claims 10, 30,39).

DE 2457424 disclose that zinc orotate is effective against cancer, with zinc being the active component and the orotate anion increasing bioavailability of the zinc (pages 1-3).

Hershler (US Pat. 4,514,421) disclose that administration of methylsulfonylmethane (MSM) and ascorbic acid and that administration of MSM resulted in reduction of tumor mass (Column 12, lines 7-47).

Hershler (US Pat. 4,616,039) disclose that methylsulfonylmethane is an assimilable source of sulfur (Abstract).

Memnon et al. disclose that vitamin C inhibits tumor growth (Abstract).

Maramag et al. disclose that vitamin C been suggested to be a protective agent against cancer development and a therapeutic agent against established cancer (Page 188). It is disclosed that vitamin C inhibited proliferation and survival of cancer cells and that preliminary results in an in vivo study showed that PC3 tumors responded to vitamin C treatment (page 194).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the use of copper orotate, manganese orotate, iron orotate, sodium salicylate, a source of assimilable sulfur and vitamin C. However, the prior art amply suggests the same as the prior art discloses dietary supplements which combine various nutrients, such as copper, manganese, vitamin C with salicylates for use in women and reducing the risk of cancer, the combination of sodium salicylate and salts of orotate to increase the efficacy of the sodium salicylate, the use of copper, manganese, iron and vitamin C for use in pregnant women and reducing the risk of cancer, MSM for treatment of cancer. Further, the prior art disclose and/or suggest that zinc orotate, ascorbic acid and sodium salicylate (NSAIDS) are effective neoplastic diseases. Finally, a composition containing ascorbic acid, manganese gluconate and copper gluconate is disclosed to be effective against cancer and that vitamin C has both protective and treatment activity against cancer. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art by providing the copper, iron, zinc and manganese as salts of orotate so as to increase the efficacy of the sodium salicylate and to combine copper, iron, zinc and manganese with sodium salicylate and vitamin C with the expectation that the composition would be suitable for use in pregnant women and for treatment of cancer, to further add MSM as it is effective in treating cancer.

Examiner has duly considered Applicant's arguments but deems them unpersuasive for the reasons set forth in the prior Office Action.

The Supreme Court in *KSR International Co. v. Teleflex Inc.*, held the following:

(1) the obviousness analysis need not seek out precise teachings directed to the subject matter of the challenged claim and can take into account the inferences and creative steps that one of ordinary skill in the art would employ;

(2) the obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents;

(3) it is error to look only the problem the patentee was trying to solve-any need or problem known in the filed of endeavor at the time of invention and addressed by the prior art can provide a reason for combining the elements in the manner claimed;

(4) it is error to assume that one of ordinary skill in the art in attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem-common sense teaches that familiar items may have obvious uses beyond their primary purposes, and in many cases one of ordinary skill in the art will be able to fit the teachings of multiple patents together like pieces of a puzzle (one of ordinary skill in the art is not automaton);

(5) it is error to assume that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try". *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396, 1397 (U.S. 2007).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor

is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 208 USPQ 871 (CCPA 1981). As such, not withstanding the Applicant's description of the various references, there is no requirement that each references recited each element of the claimed invention individually. Further, the Applicant's reason argument appears to be nothing more than a motivation argument which again is not required under KSR. In any case, the Examiner has provided reasoning to combine the references as indicated above.

The Applicant argues that since combinations are not expressly disclosed that there is no reason to combine the compounds. However, as indicated above, the prior art does disclose combinations of compounds which are effective against cancer. Further, even if the prior art did not expressly disclose combinations of compounds effective against cancer. It would be obvious to combine compounds which are effective against cancer with the expectation that the combination would be effective against cancer. There is no requirement that the references must expressly disclose or suggest such a combination. The mere fact that there hundreds or thousands of possible combinations does not make the combination nonobvious. See *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.); *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held prima facie obvious). Clearly, there are hundreds and thousand of possible combinations of detergents or herbicides, nonetheless, the combinations above were found to be obvious.

The speculation that additional compounds could add adverse effects is insufficient to overcome the rejection. See e.g. *In re Jansen*, 187 USPQ 743, 745, 746 (C.C.P.A. 1975) (whether members of the medical profession would agree or disagree as to the safety of the drug combination cannot control the determination of obviousness of the claimed drug combination and method of treatment using the same). Obviousness does not require absolute predictability. The Applicant's arguments would create a standard of obviousness where the combination itself would have to be tested to show that the combination is both safe and effective. Such a standard would equate to anticipation and is not required for a finding of obviousness.

The Applicant has submitted two Section 132 declarations as evidence of unexpected activity. However, these declarations and that the data in the Specification only show that sodium salicylate, ascorbic acid, copper gluconate and/or orotate and manganese gluconate and/or orotate are effective as anti-tumor agents. The claims are broader is scope in that they do not require the source of minerals be in the form of orotate or gluconate salts. See *In re Greenfield*, 571 F.2d 1185, 1189, 197 USPQ 227, 230 (CCPA 1978) (evidence of superior properties in one species insufficient to establish the nonobviousness of a subgenus containing hundreds of compounds); In re Lindner, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972). In any case, the prior art does disclose a composition containing copper gluconate, manganese gluconate and ascorbic acid which is effective against cancer. Since sodium salicylate is also suggested to be effective against cancer, one of ordinary skill in the art would have reason to add sodium salicylate to the same with the expectation that the combination would be effective against cancer.

Although the claims are dependent on claim 105, because the claims appear to be broader in scope than then claim 105, i.e. allowing other active ingredients, as indicated in the objection and 112 2nd paragraph rejection above. The rejection is maintained with respect to the dependent claims above.

As such, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Wednesday and Thursday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
May 12, 2009

/John Pak/
Primary Examiner, Art Unit 1616